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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,147	07/09/2001	Nicholas B. La Thanguc	620-149	4292
23117	7590	10/20/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/900,147

### Applicant(s)

LA THANGUE ET AL.

### Examiner

MISOOK YU, Ph.D.

### Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004 and 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) 33-35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 21-32, and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 April 2004 has been entered.

### ***Election/Restrictions***

Claims 33-35 and 37 drawn to method remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) for reasons in the Office action mailed on 6/18/2003.

Claims 21-37 are pending and claims 21-32, and 36 are examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

The Declaration by Professor Robert Brown is not filed according to the rules and regulation governing the U.S. patent system.

### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 07/21/2004 has been accepted.

***Sequence Rules, Withdrawn***

The objection of the specification is withdrawn in view of the corrected drawing to Fig. 1.

***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claims 30 and 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment.

***Claim Rejections - 35 USC § 102***

Claims 22-24, and 32 remain rejected, and claims 27, 30, 31, and 32 are newly rejected under 35 U.S.C. 102(e) as being anticipated by US Pat 5,863,757 (filing date of May 11, 1995).

Claims are interpreted as drawn to a fragment of SEQ ID NO:1 (claims 22-24). Claim 27 is interpreted as drawn to a polypeptide comprising SEQ ID NOs 2-7 as the first portion, wherein said polypeptide further comprises a sequence of amino acids not naturally contiguous to the first portion in DP-1. Claims 30-32 are broadly interpreted as drawn to composition comprising a polypeptide comprising SEQ ID NO:1 or fragment thereof and pharmaceutically acceptable carrier (claims 30, 32) or a cytostatic or cytotoxic agent (claim 31).

Applicant argues that the claims as now presented read "consisting of" rather than "consisting essentially of", the instant claims specify that SEQ ID NO:1 can contain from 1 to 5 additional amino acids only and that those amino acids must be at either the N- or C-terminal of the polypeptide of SEQ ID NO:1, and the polypeptide of SEQ ID NO:1 either with or without the 1 to 5 additional amino acids at the specific

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locations recited is not taught by the cited art. These arguments have been fully considered but found unpersuasive for the following reasons:

SEQ ID NO:13 (listed in column 37 and 38) of US Pat 5,863,757 is a fragment of SEQ ID NO:1 (i.e. amino acid residue #5 to 21), thus anticipating instant claims 22-24, and also anticipating the active ingredient part of instant claim 30. As for claims 27, with the transitional phrase "comprises" with the preamble "A polypeptide" reads on the GST tagged fragment of Dp-1 shown at Fig. 7b of the patent since the GST tag is a sequence of amino acids not naturally contiguous to the first portion in DP-1. As stated before, the patent teaches at column 6 teach various formulation suitable for oral, topical, parenteral administration. For claim 31, the instant specification at page 15, 2<sup>nd</sup> paragraph says that immunomodulatory compound is a cytotoxic or cytostatic agent. Therefore the various antibodies and fragments at column 6 of the patent are considered as cytotoxic or cytostatic agent.

The rejection of claim 5 under 35 U.S.C. 102(e) as being anticipated by US Pat 5,859,199 (filing date of May 15, 1996) is **withdrawn** in view of the amendment.

***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claims 23 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

***The Following Are the New Grounds of Rejection***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-32, and 36 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. Claims 21-32, and 36 as written, do not sufficiently distinguish over proteins, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

#### ***Claim Rejections - 35 USC § 112***

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "the *Drosophila melanogaster* antennapedia protein" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

Claims 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Chin-Lee et al., (May 1995, Molecular and Cellular Biology, vol. 15, pages 2536-2546).

Claims 27 and 28 are interpreted as drawn to a polypeptide comprising SEQ ID NOs 1-7 as the first portion, wherein said polypeptide further comprises a sequence of

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amino acids not naturally contiguous to the first portion in DP-1, wherein said polypeptide further comprises a transmembrane signal (claim 28).

Chin-Lee et al., teach a human DP-2 protein at page 2538. The protein of Chin-Lee et al., shown at Fig. 1A comprises instant SEQ ID NOs 1-7 as the first portion, wherein said polypeptide further comprises a sequence of amino acids (i.e., a human DP-2) not naturally contiguous to the first portion in DP-1.

As for claim 28 drawn to a membrane translocation sequence, the art does not teach where in the human DP-2 lies a nuclear transmembrane signal. However, Apostolova et al., J Biol Chem. 2002 Sep 13;277(37):34471-9, teach that the human DP-2 inherently has a nuclear membrane translocation sequence. Note the abstract. Thus, the protein of Chin-Lee et al., shown at Fig. 1A inherently comprises a membrane translocation sequence.

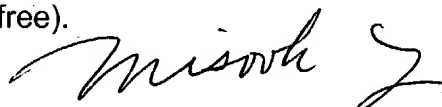
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Misook Yu', with a stylized flourish at the end.

MISOOK YU, Ph.D.  
Examiner  
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